NATIONAL CONSENSUS CONFERENCE ON TUBERCULOSIS CONTROL

10-11 November 1997
New Delhi

सत्यमेव जयते

Central TB Division
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhavan, New Delhi 110 011

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DIRECTOR GENERAL

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MESSAGE

National TB Control Programme, despite being in operation for more than 35 years, has not made any significant dent in the epidemiology of tuberculosis and the disease continues to be the leading infectious killer of adults. One important reason for the poor performance of the programme has been insufficient involvement of medical colleges leading to some reservation in the full commitment of some technical experts regarding the national strategies for tuberculosis control.

With this background, a National Consensus Conference on Tuberculosis Control was convened in Delhi in which leading experts from medical colleges throughout the country were invited to discuss various issues pertaining to the control of tuberculosis. The meeting was also addressed by international representatives including Sir John Crofton and Professor John Sbarbaro - two of the leading luminaries in the field of tuberculosis in the world.

At this Consensus Conference, various issues relating to TB Control were deliberated upon in detail. It is highly significant that the conference resolution called on the medical community to give its full support to the Revised National Tuberculosis Control Programme (RNTCP). You will see from the enclosed proceedings of the conference that the RNTCP was described by this important gathering as "perhaps the only chance of controlling tuberculosis in India in this generation."

I seek your wholehearted commitment to the cause of control of tuberculosis. You may also like to send yourcomments/suggestions, if any, to the Directorate General of Health Services (TB Division) .

With good wishes,

(S.P. AGARWAL)
27/X/98

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D.O.No. Z-28015/40/97-TB

Dated 12th November, 1998.

Dear Doctor,

A meeting had been convened to establish a national consensus on the diagnosis and treatment of tuberculosis.

Enclosed herewith are the proceedings of this conference, and a Message from the Director General of Health Services.

I shall appreciate it if this material is given a wide circulation.

Any comments or suggestions are welcome.

With regards,

Yours sincerely,

(DR.G.R.KHATRI)

CONTENTS

BACKGROUND

Tuberculosis is one of India's most serious health problem. Despite a long and distinguished tradition of tuberculosis research in India and the existence of a national programme since 1962, tuberculosis remains an all-too-common cause of illness and death. India accounts for 28% of the global burden of tuberculosis, and every day, more than 1,000 people die from tuberculosis in India—more than 1 person every minute.

In the past few years, a Revised National Tuberculosis Control Programme (RNTCP), grounded in Indian realities, has been evolved. This programme was pilot tested in 1993, and its phase-wise expansion is planned. Quality of diagnosis and results of treatment have been excellent, yet it has been observed that there is a lack of knowledge about and, in some cases, agreement with the approach taken.

In this context, it was decided to convene a National Consensus Conference on Tuberculosis from 10 to 11 November 1997 at New Delhi. Leading national luminaries and senior professionals from institutes and medical colleges were invited to discuss and debate about the most effective strategy for tuberculosis control.

The discussions have been summarized. It will be noted that participants initially had some reservations about the strategy and, more importantly, the feasibility of implementation of the revised strategy in the Indian context. However, after discussing the issues threadbare and reviewing the results of RNTCP implementation to date, the participants unanimously endorsed the strategy and went so far as to resolve that, 'Phased and effective implementation of the RNTCP is the best strategy, and perhaps the only chance of controlling TB during this generation'.

This booklet aims to disseminate the discussions and recommendations of this important gathering more widely, for use by all concerned.

MESSAGES

I have found these few days in India immensely exciting. I have been very impressed by the outstanding success of the present pilot projects of the RNTCP which have obtained very high cure rates. They show what can be achieved in India. It is a great achievement by those who have worked so hard. This two-day conference has been equally exciting in demonstrating the support of national academics and medical opinion leaders to the success of the programme. The world is watching India. We now know that India **can** do it. Now you will do it!

Sir John Crofton

Tuberculosis is a disease both of the individual and of society. Its spread is dependent upon human environment and behaviour. Therefore, it can only be controlled by society. Control will require intense cooperation between the country's government, its medical colleges and private practitioners. India's National Consensus Conference has resulted in an unprecedented commitment by all parties to make tuberculosis control a reality.

India led the world in advancing knowledge on how to treat tuberculosis. Now it can lead the world in controlling tuberculosis and diminish forever the spectre of multidrug-resistant tuberculosis.

Professor John Sbarbaro

INAUGURAL SESSION

Dr GR Khatri, DEPUTY DIRECTOR GENERAL (TB)

I welcome you all to this important event. This meeting should be both the beginning and the continuation of a national effort to meet a vital national need—the control of tuberculosis and its eventual elimination as a public health problem.

Today, tuberculosis is killing more people than ever before. Fortunately, now we have a breakthrough treatment that can permanently cure tuberculosis in six months without a single day in hospital.

Tuberculosis is killing one of our countrymen every minute. The primary objective of the conference is to enlist the inputs and support of leading national experts in the field of tuberculosis. The conference will discuss the experiences of the Revised National Tuberculosis Control Programme (RNTCP). Issues to be discussed include optimum ways of diagnosing and treating tuberculosis and ways of improving coordination.

Dr G Ramdas, ADDITIONAL DIRECTOR GENERAL OF HEALTH SERVICES

Tuberculosis is the oldest disease known to mankind. About one third of the world's population is infected, and an additional 300 million will become infected in the next decade. Deaths from tuberculosis account for 25% of all avoidable deaths among adults in developing countries. Ninety-five per cent of TB cases and 98% of TB deaths are in developing countries. India has about 2 million new TB cases every year. Every minute in India, one person dies due to TB and another 2 become sputum-positive cases.

The National Tuberculosis Control Programme was started in 1962. The implementing unit is the District TB Centre and the National Tuberculosis Institute at Bangalore is collecting and disseminating data. We find that the treatment completion rate is about 30%. In 1992, the Government of India appointed a review committee of national and international experts and they evolved a revised strategy. In this conference, we will learn about the strategy designed for the Indian context, and the results of this strategy.

Shri JVR Prasada Rao, ADDITIONAL SECRETARY, MINISTRY OF HEALTH AND FAMILY WELFARE

I will confine myself to the twin problems of HIV/AIDS and TB, and to the challenges that we are going to face in this country.

The TB and HIV nexus is posing a great threat, and more than half of all AIDS patients in India develop TB. It is estimated that by the year 2000, 14% of all

TB cases in the world would be attributed to HIV. The HIV epidemic spurs the spread of TB and increases the risk for the whole population.

Because of immune suppression, TB progresses faster in HIV-infected persons and is more likely to be fatal if not diagnosed timely or if inadequately treated. One of the most important problems is that smear-negative TB is much more common in HIV patients. Sputum microscopy is a specific test but has a low level of sensitivity which is further reduced by the presence of HIV infection.

This situation emphasizes the importance of quality sputum microscopy. The RNTCP is providing such facilities through a network of microscopy centres across the country. Quality control is being given top priority, as is rigorous training and retraining of personnel.

Increased rates of relapse are of concern for HIV/TB patients. The diligent practice of the DOTS strategy is the only answer to counter the problem. Stringent supervision is an important component to ensure adherence to treatment by HIV/TB patients until they are cured.

Dr SP Agarwal, DIRECTOR GENERAL HEALTH SERVICES

Many patients with tuberculosis first seek care from private practitioners. In areas where the RNTCP is operating, the challenge is to improve coordination between private practitioners and the government sector. One of the goals of the RNTCP is to improve that coordination, so that private doctors can know that they can get 100% reliable sputum microscopy services for their patients free of charge at government microscopy centres and that free of cost good quality potent drugs can be given to their patients through the RNTCP. The private doctor should be able to demand and receive from the RNTCP information on the patient's diagnosis and treatment. Effective coordination must be established at the local level.

In India's fiftieth year of Independence, we are proud of having created a massive infrastructure for delivering health services. However, covering the entire country with DOTS will require more than 30 million sputum examinations every year, more than 100,000 per day; an estimated 750,000 patients would be under treatment at any point in time requiring more than 100 million treatment observations—more than 350,000 per day. More than 10,000 laboratories will need to be upgraded, supplied with binocular microscopes and reagents, staffed and supervised; more than one million staff, including a lakh of doctors, will need to be trained. These are enormous challenges, but I am certain that through the collective wisdom and efforts of all concerned, practical solution for phased and effective implementation of RNTCP will be found.

Sir John Crofton

I feel rather humble before your tremendous problems. The first joint research venture between your Council for Medical Research and the British Medical Research Council in Madras (Chennai) showed that you could get just as good results by closely supervised treatment in Madras slums as by admitting patients to hospitals and giving the same treatment. This was an enormous advance for any developing country and we copied it in the UK. Research also demonstrated that intermittent treatment worked, and India was the first place it was tried. Directly supervised treatment was a way to make sure that patients completed their treatment.

The RNTCP, which has started in a pilot way, has demonstrated enormously encouraging results. If there is a genuine problem of multidrug resistance, it can only be prevented and reversed by using the recommended regimens under direct observation.

Professor John Sbarbaro

Most of the world's knowledge of tuberculosis comes from India. Directly observed therapy, which has worked in small areas around the world, can cure patients and stop the spread of tuberculosis. If it can be done, then India can do it. And if India can do it, we have an answer for the rest of the world.

This is an important conference for India and for the rest of the world. It is an honour and a privilege for me to be here with you.

Shri PP Chauhan, Secretary (Health), Ministry of Health and Family Welfare

The success achieved in the pilot programme using the revised strategy demonstrates convincingly in a population of 18 million that DOTS can work in India. In the next three years, the RNTCP is to be implemented in a phased manner for a population of more than 300 million spread over 102 districts. Additionally, 203 SCC districts will be strengthened by the year 2000. One lakh fewer patients will die each year of TB as a result of implementation of these efforts. The Planning Commission has agreed to 100% Central funding of anti-TB drugs from this year (1997) so that an uninterrupted anti-TB drug supply is ensured.

Since the top people both from the research and implementation field are present here, you may try to reach a consensus on two very important issues—one is the strategy adopted by the RNTCP—whether it is the right strategy. Second, on

DOTS itself because, while framing the RNTCP, dissenting voices were heard from within the country.

A very strong monitoring and supervisory system is needed, or else gaps in the programme cannot be identified. Awareness is another area where concentration is needed.

Shri Alok Perti, JOINT SECRETARY, MINISTRY OF HEALTH AND FAMILY WELFARE

It is my proud privilege today to offer a vote of thanks. Much has already been said about the programme, the magnitude of the TB problem, the issues involved, and we all look forward to the debates and discussions which will take place over the next couple of days. I would like to thank Shri PP Chauhan, Union Health Secretary, to have spared his valuable time to inaugurate this National Conference. We have two distinguished international personalities, Sir John Crofton and Professor John Sbarbaro, who have travelled a long distance to attend this meeting and visit other areas of our country. We welcome them and are grateful to them for having come here to attend this conference.

I thank Dr SP Agarwal, Director General Health Services and Shri JVR Prasada Rao, Additional Secretary, Ministry of Health and the person in charge of this programme. I would also like to thank Dr G Ramdas and Dr GR Khatri for participating so actively in this programme. There are a number of people from various states, medical colleges and other institutions who have been associated with the Tuberculosis Control Programme. There are people from international agencies, Armed Forces and several from the Directorate General of Health Services in the Ministry who have come here to make this Conference a success. I thank them all for sparing their time and being here with us today.

THE EDINBURGH EXPERIENCE

Sir John Crofton, MD, FRCP (Edinburgh), FRCP (London),
Former Dean, Faculty of Medicine, University of Edinburgh, and President, Royal College of Physicians

I've been seeing TB for very many years in a good many countries. What I'm going to say is related to experience in other countries and a very limited amount of what I've seen in India. I shall give a historical review of the research and actions leading up to the modern DOTS TB control system.

In the 1940s and 50s, the British Medical Research Council and the US Medical Council showed that chemotherapy was effective. In the 1950s, our Edinburgh group found that failures were due to drug resistance. We found that by giving the three drugs available at that time together, resistance could be prevented. Our most astonishing finding was that giving directly observed, effective anti-TB treatment to known cases produced a dramatic decrease in incidence.

The British and Indian Medical Research Councils found that intermittent treatment worked, and that directly observed chemotherapy was the best way of making sure that patients take treatment.

In a DOTS programme, there must be government commitment. Passive case-finding by sputum microscopy is necessary. Short-course chemotherapy must be given to sputum-positive patients, directly observed, particularly in the intensive phase. Another essential component is regular supply of reliable drugs, which also means that proper buffer stocks must be there.

COMPONENTS OF THE DOTS STRATEGY

- Government commitment
- Case-finding by microscopy
- Directly observed treatment
- Regular drug supply
- Systematic monitoring

People must be encouraged and told in health education that the treatment is highly effective, but only if taken regularly and completely. There must be a

system for preventing defaults and for recalling defaulters. The most important aspect in preventing default is how the patient is treated when he comes to the clinic—kindness, education, patience. Systematic follow-up by cohort analysis is also essential.

How accurate are X-rays in diagnosis? Observer differences are great, and there is no proof of who is right. Observer variations between a standard set of sputum smears are far smaller, and thus sputum microscopy is far more accurate and cost-effective.

Statistics show that the WHO-recommended retreatment regimen is highly effective. Theoretically, one might think that for the small number of patients who remain smear positive after treatment with 4 drugs, and who then get 5 drugs in Category II, this is violating one of the cardinal principles of TB treatment of not adding a single drug to a failing regimen. But most of these failures are not due to genuine failure of first-line treatment, but failure to administer it properly and to ensure that the drugs were taken.

> ***" Persistent treatment discipline with proved regimens is the key to success."***

Medical leadership can help governments realize that they have a major problem of tuberculosis and that it can be solved. Technical and financial help is necessary. Local leadership is absolutely essential. Integration with routine services was not very effectively done for years but now it has been shown that it can be done. There should be national and international motivation, extensive consultation (what we're doing today), good supervision, encouragement and communication between units, training and retraining.

Unreliable chemotherapy is the major cause of drug resistance. Unsupervised chemotherapy, especially during the intensive phase, is particularly dangerous.

> ***" The most important aspect in preventing default is how the patient is treated when he comes to the clinic: kindness, education, patience and systematic follow-up by cohort analysis."***

Changing and individualizing treatment for no good cause (minor side-effects) leads to resistance. Doctors often panic and change drugs. We've learnt by our experience that if you know you are giving reliable chemotherapy and you know that the patient is taking it, you should keep your courage up—persist; don't mess about or you can cause harm. Persistent treatment discipline with proved regimens is the key to success.

Among the Third World problems, one is that of irregular drug supply. Consider a doctor working in the periphery—there is only one drug because of bad supply, and a patient is desperately sick. Does the doctor give the one drug and save the patient's life and risk resistance, or does he let the patient die? Patient ignorance is often blamed, but it is always the doctor's fault. Studies show that with 2–3 drugs, isoniazid-resistant cases have a failure/relapse rate of 33%. With a 4-drug combination the failure/relapse rate is 1% and with 5 drugs 0%. That is why 5 drugs are used in the retreatment regimen recommended by the WHO.

" Obstinate individualism is the enemy of success."

Resistance is often misdiagnosed. When there is a relapse or failure, more often it is actually because the patient has not completed treatment. A study in the Bombay (Mumbai) slums showed that 60% of patients went first to private doctors, only half of whom were formally trained. Eighty different regimes were prescribed by 102 doctors, generally more expensive than the most expensive of standard regimens! Can you imagine a better prescription for producing drug resistance?

The conclusions about drug resistance are—all acquired resistance is the doctor's fault. Hence, all drug resistance is preventable. Preventing acquired resistance will prevent primary resistance. Cooperative effort and the importance of a National Programme is the secret of success, and obstinate individualism is the enemy of success. In India, your coming HIV epidemic makes the success of this project particularly urgent.

KEY POINTS

- Sputum microscopy is a more reliable diagnostic tool than chest X-ray for diagnosis of pulmonary TB.
- Unreliable chemotherapy is a major cause of drug resistance.
- Drug resistance is often misdiagnosed.
- Most treatment failure is failure to ensure drug intake, rather than failure of chemotherapy.

THE AMERICAN ALLEGORY

Professor John Sbarbaro, MD, MDH, Professor of Medicine and Preventive Medicine, University of Colorado

Those who do not learn from history are doomed to repeat it. I want to take you to the United States and show you how a very industrialized country can do just about everything wrong. In 1953, our case rate was around 57 per 100,000. In 1984, it was down to 9.4. The Director at the Centers for Disease Control, Atlanta said that with a 74% decline, it was an ideal opportunity to eliminate tuberculosis. He called for the creation of a committee—the Advisory Council on the Elimination of Tuberculosis. We aimed to get down to 3.5 cases/million by the year 2000 and 1.0 case/million by 2010. Two or three years after we published our strategic plan to eliminate tuberculosis, tuberculosis was out of control in many parts of the country. HIV was coming and clearly we were having reactivation of tuberculosis. There was drug and alcohol abuse, non-compliance and American doctors were not treating patients correctly. The real reasons were a complete failure of our political leadership—we had defunded and eliminated all our programmes. Second, we had a failure of public health leadership and third, failure of our physician leadership. Because of these factors, our patients had failed to get appropriate therapy and our problems started.

ERRORS MADE IN TB CONTROL IN THE UNITED STATES

- Failure of political leadership to provide funding
- Failure of public health leadership
- Failure of physician leadership

Most patients do not take their drugs regularly. Age, sex, race, religion, socio-economic status, occupation, marital status and education do not make a difference to drug compliance.

How do we ensure that patients take their medications? You gave us the answer at the treatment centre in Madras (Chennai). The TB Research Centre noted in 1962 or so that intermittent treatment with supervised therapy was equally effective. A central feature of this programme was a network of adequately staffed neighbourhood treatment centres (Primary Health Centres), with timings conforming to patients' living patterns and waiting time reduced to an absolute minimum. Persistent follow-up was another key feature.

Some physicians believe that requiring individuals to take their medication in the presence of a responsible body would entail unacceptable assump-tions about the future behaviour of those under care. This objection totally ignores the fact that one out of three patients does not take medicines.

> ***" Most patients do not take their drugs regularly. Age, sex, race, religion, socio-economic status, occupation, marital status and education do not make a difference to drug compliance."***

Directly administered therapy is a service to the patient and a service to the community—you cure the patient and you protect the community. Directly observed therapy has been viewed by some as an imposition that could be justified only in the presence of evidence that the patient would behave in a way that would pose a threat to public health. In other words, get multiple drug-resistance first, then we will believe that you don't take your pills!

What have we learnt in the US? First, we have learnt the value of maintaining a centre for TB expertise, with commitment and creativity at the national level. Second, there is a need to maintain ongoing and effective TB surveillance programmes. Third, there is a need to maintain public health regulatory and supervisory control over the TB medications given by general physicians.

What gets measured gets done. If you don't measure results, you cannot separate success from failure. Countries in which university scientists involve themselves in the implementation of training programmes are more successful. When there is no synergy between public health and universities, there will be failures.

WORKING GROUPS

After the inaugural session, the participants were divided into four working groups, each with a separate charge.

Group 1 discussed issues pertaining to the diagnosis of tuberculosis. The Chairman of this group was Dr VK Arora, Director, Professor, and Head of Department, Chest and TB, JIPMER, Pondicherry and the Co-Chairman was Dr PR Narayanan, Director, TRC, Chennai. This group reviewed the evidence for different strategies of the diagnosis of tuberculosis, determining whether the RNTCP strategy is correct and recommending steps for further improvement.

Group 2 discussed issues about the treatment of tuberculosis. Dr SK Agarwal, Professor of Chest and TB, BHU, Varanasi was the Chairman of this group. The Co-Chairman was Dr R Sarin, Chest Specialist, LRS Institute for TB and Allied Diseases, New Delhi. This group was charged with reviewing the evidence for different daily and intermittent tuberculosis regimens, determining whether the regimens recommended under the RNTCP are effective and appropriate, and recommending steps for further improvement.

Group 3 discussed issues in the administration and organization of anti-tuberculosis treatment. The Chairman was Dr P Jagota, Director of NTI, Bangalore. This group reviewed the evidence for different means of ensuring that patients receive medicines, listing the necessary inputs for effective programme implementation, examining the RNTCP strategy and inputs, and recommending steps for further improvement.

Group 4 discussed the issue of coordination of tuberculosis control services with the private sector including NGOs in the Indian context. The Chairman was Dr Harish Grover, who is in charge of the tuberculosis programme for the Indian Medical Association (IMA). This group reviewed means to involve different sectors of the health and social system, and with suggesting specific steps for involving these groups.

Each of these groups met for two days and had extensive discussions and deliberations. At the end of their sessions, each group devised and agreed on a set of specific recommendations. After the groups had finished their work, the entire conference met again in a plenary session to review the work of each of the groups and draft the conference resolution. This plenary session was chaired by Dr SP Agarwal, Director General of Health Services. In this plenary session, each group presented their findings and recommendations, which were again discussed in detail. Changes in the proposed recommendations were made. The conference then drafted a resolution expressing the essence of the workshop. Finally, the resolution and recommendations were put to a vote and all were unanimously adopted.

Conference Resolution

The Revised National Tuberculosis Control Programme (RNTCP) is based largely on Indian tuberculosis research. Since 1993, India has adapted and refined this strategy. Reported results of the RNTCP are encouraging. Despite the availability of effective treatment, tuberculosis remains one of India's most pressing health problems, and multidrug-resistant tuberculosis has the potential to undermine efforts to control the disease. Phased and effective implementation of the RNTCP is the best strategy, and perhaps the only chance of controlling TB in India during this generation. Ensuring diagnosis and cure of TB cases by RNTCP policies is the only effective way to stop the spread of multidrug-resistant TB in India.

We, the tuberculosis experts, hereby call on all health professionals in public and private sectors to extend their full cooperation in implementing the RNTCP more widely in India.

RECOMMENDATIONS

GROUP 1

Diagnosis of Tuberculosis

1. Sputum microscopy is the primary diagnostic tool for pulmonary tuberculosis. Diagnosis of tuberculosis should be done systematically in patients attending health facilities. Three sputum smears for AFB should be obtained from all patients with cough for 3 weeks or more. Topmost priority should be given to diagnosing and curing patients with sputum-positive tuberculosis as these patients are the source of infection in their community and because they have the highest risk of dying of pulmonary tuberculosis.
2. Unlike strategies in other disease control programmes, efforts to find tuberculosis patients in the community through active search or diagnostic camps should never be undertaken. Studies in India conclusively show that the vast majority of tuberculosis patients present to medical facilities soon after the onset of illness. Efforts at education should be directed towards the health staff to ensure that all patients with cough for 3 weeks or more undergo sputum examination in a competent laboratory. Active case-finding in the community will have little yield as compared to the inputs, and will substantially increase the number of patients who are likely to receive incomplete treatment and are therefore likely to develop drug-resistant tuberculosis which they then will spread to their family and community.
3. X-ray should not be used as the primary diagnostic tool for tuberculosis because it is non-specific and will result in over-diagnosis of active tuberculosis. However, X-ray is an important complementary tool in the diagnosis of smear-negative patients and for those who have only a single positive smear.
4. Intensive education should be disseminated about the free availability and location of diagnostic centres. Sputum microscopy services with systematic quality control should be established by the government and used as a diagnostic resource by the medical community.
5. Sputum microscopy centres for diagnosis should be placed in all medical colleges in RNTCP districts. These can also be used as training centres.
6. The expertise available in the medical colleges can be used for training purposes for which the core faculty at medical colleges may be trained at Central Institutes.
7. Mantoux testing has no role in the diagnosis of TB above the age of 5 years. ELISA, PCR, rapid culture methods and other sophisticated tools are also not recommended for diagnosis under programme conditions.

GROUP 2

Treatment of Tuberculosis

1. Regimens, modes and duration of administration recommended by the National Tuberculosis Programme and the Revised National Tuberculosis Control Programme (RNTCP) are effective and are recommended to be used by all medical practitioners. The number of pills in the combipack should be reduced if possible, maintaining the same dosages.
2. Experience with current dosage in terms of efficacy and toxicity in different weight groups (especially less than 30 kg and more than 60 kg) should be systematically evaluated in India, and based on this information, policy modified, if necessary.
3. A regular and reliable supply of good quality anti-tuberculosis drugs must be ensured. Facilities treating TB patients under the RNTCP should have patient-wise boxes in place to ensure that patients who are begun on treatment will have the full course of medications to complete treatment.
4. Anti-tuberculosis drugs should not be available without a doctor's prescription.
5. Follow-up sputum examinations are essential for determining patient progress and outcome.
6. The priority must be to implement the NTP and RNTCP in order to prevent MDR-TB, because a poorly performing programme will create MDR-TB at a rate faster than these cases can be cured, even if unlimited resources are available. A good TB control programme such as the RNTCP can prevent the emergence of MDR-TB, and can reverse the trend of MDR-TB in communities in which it has emerged. Treatment of MDR-TB is costly, toxic and often unsuccessful, and should only be undertaken in specialized centres.
7. Before any patient is labelled as a chronic case and considered for MDR-TB treatment, he should have received Category II treatment under direct observation.

GROUP 3

Administration and Organization of Anti-Tuberculosis Treatment

1. Patient's non-adherence to treatment, even if medications are available, is a serious problem which reduces the success of tuberculosis control measures and facilitating the spread of drug resistance. There are many causes for patient non-adherence, including poor interpersonal communication skills and inaccessibility of treatment facilities. The only reliable and proven method of ensuring adherence to treatment is in a well-functioning programme of directly observed treatment (DOT), in which a trained individual who is not a family member watches and assists TB patients swallow their pills. DOT should be arranged as conveniently as possible to the patient, relying on strengths and resources which exist in each community (e.g. multi-purpose workers, Anganwadi workers, trained Dais, Panchayat leaders, religious leaders, etc.). While taking due care against expansion without full preparation and ground work, the RNTCP, using DOT and short-course chemotherapy, should be implemented throughout India as rapidly as possible, while maintaining a high quality of patient services and supervision.
2. There should be systematic monitoring of and accountability for the outcomes of all patients begun on treatment for tuberculosis, particularly of those who receive regimens containing rifampicin. Standardized outcome measures, using follow-up sputum smears for patients with pulmonary smear-positive tuberculosis, should be used to evaluate and improve performance in each health facility, treatment unit, district, state, and in India as a whole. Sputum conversion rates and rates of cure, completion, failure, transfer out, default and death should be calculated according to definitions of the RNTCP and should meet the standards laid down, especially those for cure.
3. When the RNTCP is implemented in a district, the whole area of the district should be covered at the same time. All the Central, state and public sectors, viz. Armed Forces, Railways, CGHS, ESI and medical colleges, etc. should be involved and should partcipate actively. They should establish TUs and microscopy centres as per the population norms and follow DOTS strategy and RNTCP guidelines. These agencies should submit quarterly reports as per schedule on prescribed formats.
4. All RNTCP centres should be provided with the particulars of location, etc. of other RNTCP districts/subdistricts in the country so as to facilitate transferring of the patients.
5. Non-RNTCP districts should also be strengthened by providing vehicles/ drugs and required logistics at the earliest.

GROUP 4

Coordination of Tuberculosis Control Services

1. To achieve greater coordination of TB control services there is need for continued political support and commitment. There is also a need to increase public awareness, IEC activities and advocacy.
2. Governmental and non-governmental facilities providing TB services must co-ordinate better. Ways must be found by Central and State Governments to involve Railways, Armed Forces, medical colleges, ESI and NGOs in the RNTCP. These agencies should be able to ensure over 85% cure rates. In addition, private practitioners, general hospitals and District TB Centres should have a proper system to coordinate referrals for diagnosis and treatment.
3. NGOs and corporate bodies should share their experiences with the government in order to improve their programme.
4. Physicians have a responsibility toward their patients, their profession and their community. In the case of TB, their responsibility is to ensure that patients are cured and thereby stop spreading infection. This responsibility should be a central theme of teaching in medical colleges. As per Medical Council of India (MCI) recommendations, undergraduate students and interns should be posted in TB departments.
5. Leaders in the medical community such as professors in medical colleges are crucial to success in tuberculosis control efforts. They should set the standard of care, including using anti-TB regimens recommended by the Government of India. All doses of medicines given in hospital should be directly observed. In patients living in RNTCP areas, the RNTCP regimens should be given, and follow-up care including direct observation of treatment should be closely co-ordinated with the District Tuberculosis Centre/chest clinic in the area.
6. Professional updates on TB should be sent to all medical colleges for use in teaching, to the Indian Medical Association (IMA) for dissemination of information among its members, and to Directors of Health Services of states for dissemination to the hospitals and other health care outlets.
7. The IMA, public sector undertakings and NGOs may be identified as individual units so that training and IEC activities, etc. can be planned by them with regular budgeting and support.

8. The medical education curriculum should be made fully consistent with national policies on the control of TB. State medical education authorities and programme implementing authorities should meet at regular intervals to discuss consistency of the curriculum with national policies and to ensure effective coordination so as to achieve the goals of the RNTCP.
9. Funds should be committed to organize CME programmes in each district on a regular basis. The IMA should be recognized as a nodal agency for this purpose.
10. Medical colleges which adopt RNTCP and open a DOTS centre should receive the supply of drugs from the national programme.

AN INSIGHT INTO INDIA'S RNTCP

In the 1950s, Indian TB researchers documented the tremendous burden of suffering caused by TB. In the 1950s and 1960s, the modern principles of the diagnosis and the treatment of TB were established by research done in India.

The National Tuberculosis Programme (NTP), established in 1962, created an infrastructure for TB control throughout the country. A comprehensive review in 1992 determined that the programme had not achieved the desired results. To intensify the efforts to control TB, the Government of India adopted the revised strategy in 1993 in the form of DOTS.

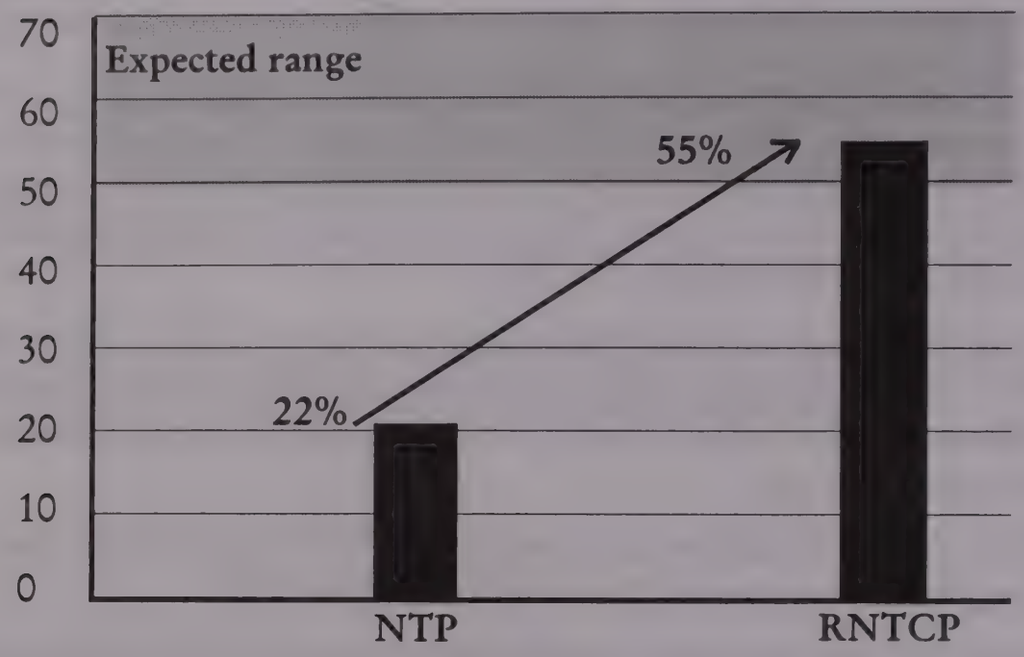
The RNTCP has been remarkably successful. In a population of more than 200 lakh in 13 states throughout the country, where presently RNTCP is being implemented, the quality of diagnosis is dramatically better than that of the previous programme.

Nearly 8 out of 10 patients diagnosed in the RNTCP since 1993 are being cured; this cure rate is more than double that of the NTP.

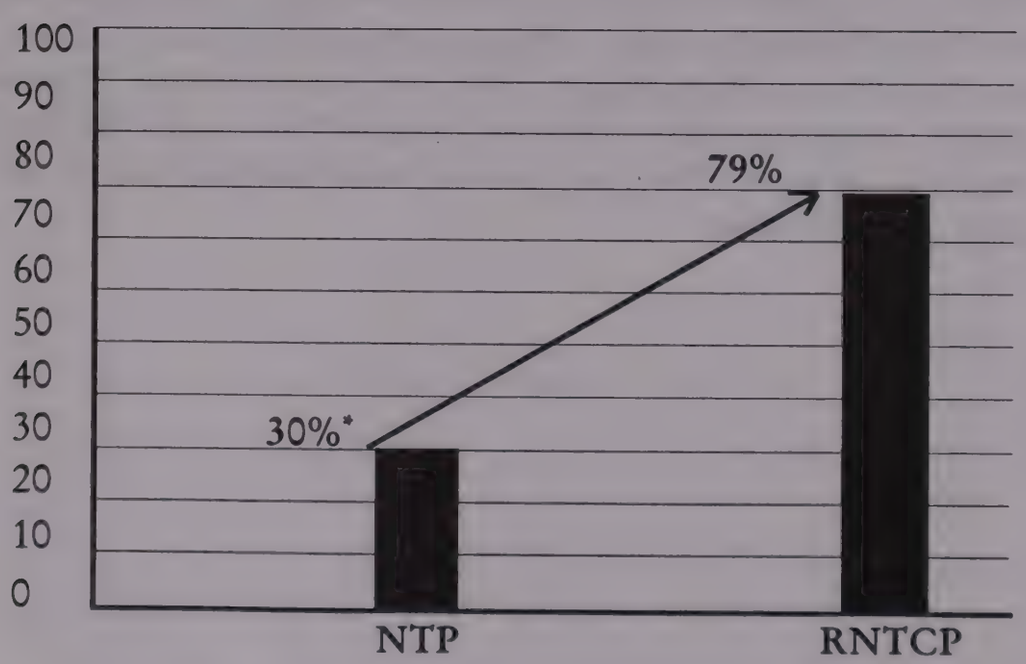
In RNTCP, 3 sputum smears are obtained for diagnosis. These are examined by a trained Laboratory Technician who uses a good quality binocular microscope. The diagnostic algorithm presented in page 21 is followed, avoiding overdiagnosis and unnecessary treatment of patients with non-specific radiographic abnormalities. As a result, more than half of the patients with pulmonary TB have laboratory confirmation by smear.

Treatment is given under direct observation with standardized regimens. All medicines are supplied in patient-wise boxes ensuring that treatment will never fail for lack of drugs. As a result, all types of patients have had excellent treatment outcomes. Even patients who remain smear-positive at 5 months of Category I treatment and are placed on Category II are usually cured with the Category II regimen—70% of such patients being cured in the most recent analysis of RNTCP data.

Quality of diagnosis: Laboratory confirmation

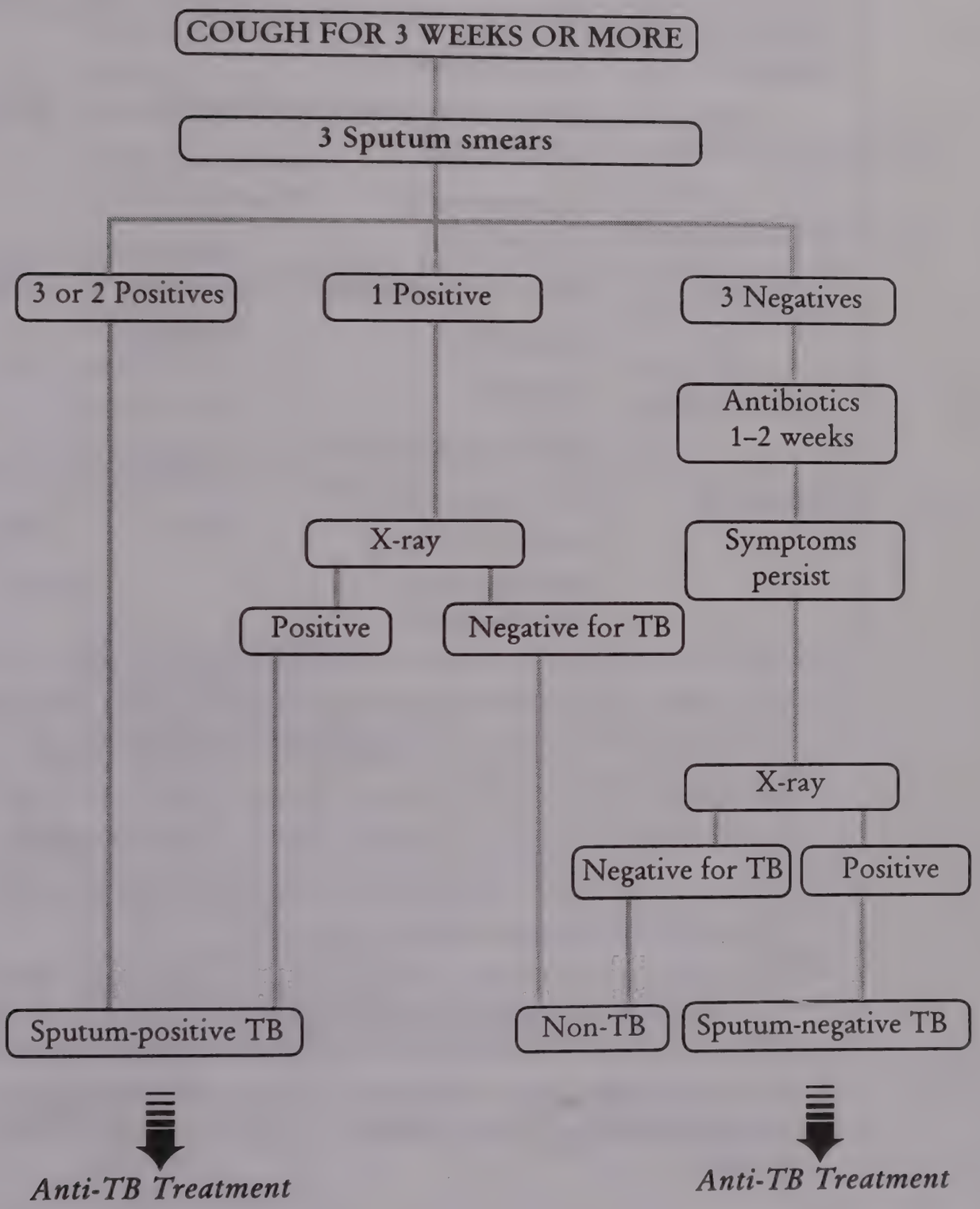


Quality of treatment: Cure/completion



* Cure not assessed in NTP; 30% of patients collect medicine for the prescribed duration

TB: DIAGNOSIS AND MANAGEMENT



RNTCP TREATMENT REGIMENS

TB Treatment	TB Patients	Intensive Phase	Continuation Phase
Category I	New smear-positive New smear-negative (seriously ill) Extra-pulmonary** (seriously ill)	$2(HRZE)_3$*	$4(HR)_3$
Category II	Sputum smear-positive: – Relapse*** – Failure*** – Treatment After Default	$2(SHRZE)_3$ $1(HRZE)_3$	$5(HRE)_3$
Category III	New smear-negative (not seriously ill) Extra-pulmonary (not seriously ill)	$2(HRZ)_3$	$4(HR)_3$

* The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old receive streptomycin 500 mg. Patients in categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.

** Examples of seriously ill extra-pulmonary TB cases are meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications and intestinal and genito-urinary TB.

*** Very rarely, patients relapse with extra-pulmonary or smear-negative pulmonary tuberculosis; such patients are considered as "Other" and treated with the Category II regimen.

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. . . Phased and effective implementation of the RNTCP is the best strategy, and perhaps the only chance of controlling TB in India during this generation. Ensuring diagnosis and cure of TB cases by RNTCP policies is the only effective way to stop the spread of multidrug-resistant TB in India. We, the tuberculosis experts, hereby call on all health professionals in public and private sectors to extend their full cooperation in implementing the RNTCP more widely in India. . . .

– from Conference Resolution